Reference) of lisinopril C_{max} and AUCs were within the accepted 80% to 125% range, indicating no significant difference.

Example J: Clinical Trial: Bioavailability Study of 10 mg Lisinopril Oral Solution vs. Zestril® 10 mg Tablets Under Fed Conditions

This study was conduct the same as in example G, with the exceptions that only 52 subjects were analyzed for pharmacokinetic parameters, and the dose administration followed a 10-hour overnight fast, followed by the ingestion of a Food and Drug Administration standard high-calorie, high-fat breakfast meal.

Results: Based on the geometric mean ratios of lisinopril AUCs (Test/Reference for AUC_{last} and AUC_{inf}), the bioavailability of the test formulation relative to the reference product was approximately 99% to 101%. The geometric mean ratio of lisinopril C_{max} was 99.45%. The 90% confidence intervals about the geometric mean ratios (Test/Reference) of lisinopril C_{max} and AUCs were within the accepted 80% to 125% range, indicating no significant difference.

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A method of treating hypertension in a subject comprising administering to that subject a therapeutically effective amount of a stable oral liquid formulation, comprising:
- (i) about 1 mg/ml lisinopril or a pharmaceutically acceptable salt or solvate thereof;
- (ii) a sweetener;
- (iii) a buffer comprising citric acid and sodium citrate;
- (iv) a preservative selected from the group consisting of sodium benzoate, benzoic acid, sorbic acid, methylparaben, propylparaben, and salts thereof; and
- (v) water;
- wherein the formulation is stable at about 25±5° C. for at least 6 months.

2. The method of claim **1**, wherein the lisinopril is lisinopril dihydrate.

3. The method of claim **1**, wherein the pH of the formulation is between about 4 and about 5.2.

4. The method of claim **1**, wherein the formulation is stable at about 25±5° C. for at least 24 months.

5. The method of claim **1**, wherein the hypertension is primary (essential) hypertension.

6. The method of claim **1**, wherein the hypertension is secondary hypertension.

7. The method of claim **1**, wherein the subject has blood pressure values greater than or equal to 140/90 mmm Hg.

8. The method of claim **1**, wherein the subject is elderly.

9. The method of claim **1**, wherein the subject is a child.

10. The method of claim **1**, wherein the formulation is further administered in combination with an agent selected from the group consisting of diuretics, beta blockers, alpha blockers, mixed alpha and beta blockers, calcium channel blockers, angiotensin II receptor antagonists, ACE inhibitors, aldosterone antagonists, and alpha-2 agonists.

11. A method of treating heart failure in a subject comprising administering to that subject a therapeutically effective amount of a stable oral liquid formulation, comprising:
- (i) about 1 mg/ml lisinopril or a pharmaceutically acceptable salt or solvate thereof;
- (ii) a sweetener;
- (iii) a buffer comprising citric acid and sodium citrate;
- (iv) a preservative selected from the group consisting of sodium benzoate, benzoic acid, sorbic acid, methylparaben, propylparaben, and salts thereof; and
- (v) water;
- wherein the formulation is stable at about 25±5° C. for at least 6 months.

12. The method of claim **11**, wherein the lisinopril is lisinopril dihydrate.

13. The method of claim **11**, wherein the pH of the formulation is between about 4 and about 5.2.

14. The method of claim **11**, wherein the formulation is stable at about 25±5° C. for at least 24 months.

15. The method of claim **11**, wherein the subject is not responding adequately to diuretics and *digitalis*.

16. A method of treating a hemodynamically stable subject within 24 hours of acute myocardial infarction comprising administering to that subject a therapeutically effective amount of a stable oral liquid formulation, comprising:
- (i) about 1 mg/ml lisinopril or a pharmaceutically acceptable salt or solvate thereof;
- (ii) a sweetener;
- (iii) a buffer comprising citric acid and sodium citrate;
- (iv) a preservative selected from the group consisting of sodium benzoate, benzoic acid, sorbic acid, methylparaben, propylparaben, and salts thereof; and
- (v) water;
- wherein the formulation is stable at about 25±5° C. for at least 6 months.

17. The method of claim **16**, wherein the lisinopril is lisinopril dihydrate.

18. The method of claim **16**, wherein the pH of the formulation is between about 4 and about 5.2.

19. The method of claim **16**, wherein the formulation is stable at about 25±5° C. for at least 24 months.

20. The method of claim **16**, wherein the formulation is further administered in combination with an agent selected from the group consisting of beta blockers, aspirin, and thrombolytics.

* * * * *